IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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UNITED STATES OF AMERICA, et al.,	:	CIVIL ACTION NO. 15-6264
Plaintiffs	:	
v.	:	Easton, Pennsylvania
	:	June 1, 2017
MEDTRONIC, INC.,	:	10:32 o'clock a.m.
Defendants	:	

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ORAL ARGUMENT ON MOTION TO DISMISS
BEFORE THE HONORABLE EDWARD G. SMITH
UNITED STATES DISTRICT COURT JUDGE

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(The following occurred in open court at 10:32 o'clock a.m.)

THE COURT: Good morning. You may be seated. Thank you.

The Court is called to order in the matter of Cathleen Forney v. Medtronic, this is Docket No. 15-6264, and the Court convenes today to hear argument with respect to the motion to dismiss that has been filed by Medtronic, Inc.

Present in the courtroom on behalf of the plaintiff is Attorney Susan Burke. Good morning.

MS. BURKE: Good morning.

THE COURT: And on behalf of the defendant, Medtronic, is Kirsten Mayer, Mitchell Stromberg, and Katherine Glaser. Good morning and welcome to Easton.

MS. MAYER: Thank you.

THE COURT: I guess we'll begin with the defendants, who have raised several issues where you believe the complaint in this case is deficient. Most interesting, of course, is this whole issue of whether a staffing kickbacks constitute a violation of the anti-kickback statute.

If you would like to proceed.

MS. MAYER: Yes, your Honor. I think that is a good place to start, because it frames the 9(b) issues as well.

I think the premise of the complaint, and in particular the opposition defending the quality of the

complaint or the adequacy of the complaint, is that if the relator alleges that free staffing or free services were provided and that at least for some of that the physician customer, you know, would otherwise have had to pay a fee for that service or incur an expense for that service, that that alone is enough to plead an anti-kickback violation.

And counsel has pointed to predominantly some guidance from OIG and fraud alerts, has pointed to some excerpts from the AdvaMed Code, in order to support that statement.

What I want to go through very briefly for your Honor, but just to highlight this critical point, is that it is crystal clear from the AdvaMed Code, the OIG Guidance to Pharmaceutical Companies, and indeed the fraud alerts that relator's counsel cites, that you can provide as a manufacturer free services and free staffing that conveys a value to the doctor, but as long as it's not independent of the product you're selling, it's outside the scope of the anti-kickback statute. It's not remuneration, because it's part and parcel of product support service that you're allowed to provide. So free services is only an issue if the service that's provided is outside of what's permitted.

And I want to make it concrete. So if you turn to the AdvaMed Code, so if you look at the AdvaMed Code, it opens on page 1 -- and I want to -- the AdvaMed Code is not a

statute or a court case, so it's not law, but it is guidance to the industry that's recognized by a leading industry organization as providing ethical compliance guidance for what is and isn't permissible conduct.

And, again, I think DOJ and also relator's counsel points to the AdvaMed Code as relevant authority in evaluating whether a free service or conduct constitutes conduct that would implicate the anti-kickback statute.

And so in the AdvaMed Code, in just page 1 to 2 for medical devices, it not only notes that many medical technologies require technical support during and after deployment, but also says that the safe and effective use of sophisticated electronic, in vitro, diagnostic, surgical, or other medical technologies often requires companies to provide health care professionals appropriate instruction, education, training, and technical support, and notes that regulators often require this type of training as a condition of product approval, which again is just another piece of information.

So we have here the notion that providing technical support, education and training enhances patient safety, is often required by regulators, but in any event is something that is appropriate for medical technology companies to do in connection with the sale of their products. But it doesn't stop there.

Further into the AdvaMed Code, the code talks about additional types of services that can be provided. For example, on pages 8 to 9 it talks about the provision of coverage, reimbursement and health economics information, and says that "as devices have become increasingly complex, so have coverage and reimbursement policies," and patient access benefits when doctors have accurate information and assistance with this.

And it says that permissible activities in this area include, but are not limited to, collaborating with health care professionals to secure coverage; promoting accurate claims by providing accurate and objective information about reimbursement and coverage; facilitating patient access by providing health care professionals with assistance in obtaining coverage, which may include providing information or training, but also providing sample letters and information on medical necessity and assistance with appeals of denied claims. It even says that "subject to appropriate privacy safeguards, the company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorization, pre-certification, and appeals relating to a company's own product." And this is the key limiting factor here.

And, you know, I won't belabor going through the pharma compliance guidance and I will spend one moment on an

OIG fraud alert that I think is directly relevant here, because what allows a company to do this without it being considered free services that implicates the anti-kickback statute is that it relates to the company's own product that it is selling. So it's that link; it's not independent of the product is the way it's viewed.

This encompasses conduct that clearly provides a value to the doctor. The way you measure that is if the manufacturer weren't providing that patient with assistance in achieving coverage or information about accurate reimbursement rules, or collaborating with the physician to achieve coverage, the physician would have to have one of his own staff do that work.

So out of the gate, if -- you know, we see here that the standard for whether something is remuneration that triggers the anti-kickback statute, the standard has to be it's not enough to say it's a free service, because we've just seen a list of services that are provided for free in connection with the sale of the product, and it's not enough to say that the physician would have to pay somebody to do the same work if the manufacturer didn't do it, because of course they would. The physician has to get paid for the claims, they would need to either hire a separate staff person or take time from an existing staff person to go do that work.

So the key question if you're going to plead free services or free staffing assistance as kickback is you can't just say that alone, you also have to plead facts that demonstrate plausibly under Rule 8 and with specificity under Rule 9(b) that the service, the conduct was independent of the product.

If you turn to the OIG fraud alerts that relator cites, which issued in 1994, there's I think a particularly helpful and instructive one towards the end of that rather short set of guidances, which talks about in the clinical laboratory, outside clinical laboratory context the provision of phlebotomy services to physicians by an outside clinical laboratory. And here the OIG in a special alert is saying that when permitted by state licensing laws, which is not at issue here, a laboratory, an outside lab may make available to a physician's office a phlebotomist to collect specimens from patients for testing by the outside laboratory.

So here we have a doctor who is buying and contracting for outside laboratory services and this is the OIG saying it's okay for that outside lab to place a phlebotomist at the outside lab's expense in the doctor's office to collect specimens from patients, provided those specimens are for testing by the outside lab. This is another example of the concept that this is a free service clearly that's being provided that the doctor would otherwise

have to pay someone in his office to do that's permitted and doesn't implicate the anti-kickback statute because it's part and parcel of that purchased outside laboratory service. So providing free service is not in and of itself something that implicates the anti-kickback statute.

This OIG fraud alert goes on to try to provide a little bit more information about what might -- where this otherwise permissible conduct could cross the line and it says the statute would be implicated, the anti-kickback statute, it is implicated when the phlebotomist performs additional tests that are normally the responsibility of the physician's office staff. These can include taking vital signs or other nursing functions, testing for the physician's own office laboratory, for performing clerical services that are not related to the collection and processing of the specimens by the outside laboratory.

So here you see OIG fleshing out the kinds of facts that would potentially implicate the anti-kickback statute. You've got an outside lab placing a phlebotomist not just to collect specimens and perform clerical functions and medical functions related to the collection and processing by the outside lab of that outside lab testing specimen, but also taking over the mind run routine nursing functions that the doctor's office would provide that's independent of the outside lab service.

The way that works in the medical device context would be, again, if you have a device manufacturer whose rep in the office supporting the product with education, technical support, troubleshooting, ensuring the doctor is using the device correctly with the patient and understanding information the doctor gets from the device and the patient, that's all product, integral to the sale of product.

However, if that rep was then also providing reimbursement advice about general ENM services or something like that, general services that the doctor provides to their patients that are unrelated to the product, that would potential -- that would be something that's unrelated to the product that might be implicated. Or if the sales rep was, you know, literally replacing the doctor and performing clinical services, right? That would be obviously exercising clinical judgment. Writing prescriptions for patients, you know, that would raise medical licensor issues and malpractice issues as well, but that's something that's different from --

THE COURT: And in trying to draw that line, isn't that where the difficulty -- part of the difficulty is this is a complaint prior to discovery, which means the available facts to the plaintiff are limited, because when do you get from -- and I'm not sure in this case, because I can't tell from the complaint -- obviously, if Medtronic sent just a

surgery nurse to just replace a surgery nurse that would otherwise be there and it had nothing specific to do with this particular device, that would appear to start be going on the side of the anti-kickback statute that it was just saving the doctor money. But even there I have a little bit of a problem, because who hires -- and I don't know what these people were doing, because if I'm assuming it's a pacemaker and I'm assuming it's during surgery, perhaps I'm assuming too much, because maybe it is counseling to the patient before, having somebody who has technical expertise in the pacemaker, what you can do, what you can't do, et cetera, if somebody like that is sent to counsel somebody who's getting the pacemaker, obviously that would be okay -- I shouldn't say obviously, but that would be okay.

If the particular implant device requires a great deal of technical skill beyond what a normal surgeon would have or even to complement the normal surgeon's expertise and you send somebody, here's the pacemaker and here's the person to help you understand this pacemaker, and we do this all the time; this is our pacemaker, we know it and we've studied it and we're going to give you some advice, if you want it, during the insertion of this pacemaker, that would seem to be fine. If on the other hand you say, hey, you know what, we're going to send you a free anesthesiologist to put the person under or we're going to send you a free surgical nurse

to help you out there and close up the surgery, then it starts to look as though it's a benefit that has a substantial independent value to the purchaser.

And I guess the question I have is, there's no question you can provide free services, in my mind, I think there's no question. It benefits the patient, it benefits the doctor, it protects the manufacturer, it makes sure the product is used the way it was intended to be used, et cetera. It's at what point -- suppose you were a very crafty medical device manufacturer and you're trying -- you can't give money outright to the doctor, you can't even take him out to dinner, what can we do for him? Well, we can reduce his staffing costs. So how are we going to compete with the others? We'll reduce your staffing cost. You buy this, Medicare will pay for it, and we'll reduce your overhead expenses.

I could see certainly, and that's what's suggested here, I could see ways that a medical device company could craft such a marketing scheme with the idea of providing this substantial, independent value to the purchaser. I just don't know from the facts in this complaint whether it's exactly as you say, you're sending technical assistance, you're sending somebody familiar with the product and it's integral to the product that is being -- and is all of this pacemakers or does it involve the stents and other things?

MS. MAYER: No, it involves all -- it all involves implantable cardiac devices, but it includes -- it's not just pacemakers, it also includes devices that have a built-in defibrillator, so that if your heart stops, it will jump start your heart.

THE COURT: Oh, I thought they were talking about external defibrillators.

MS. MAYER: No, no.

THE COURT: So that's internal?

MS. MAYER: Yes, it's internal.

THE COURT: Okay.

MS. MAYER: Yes.

THE COURT: And they're very sophisticated, complex devices.

MS. MAYER: They're computers that are implanted and regulate -- monitor and regulate the rhythm of your heart.

THE COURT: So who does Medtronic, when do they send them, and is it before surgery, is it during surgery? Who are you sending?

MS. MAYER: So what I want to do is answer your questions, at the risk of answering a question with a question, I think I want to highlight a couple really critical things here --

THE COURT: Sure.

MS. MAYER: -- in this case at this stage.

What I think is clear is you're saying I don't know what is allegedly going on here --

THE COURT: That's because the complaint is insufficient.

MS. MAYER: -- because the complaint doesn't say.

THE COURT: Right.

MS. MAYER: It doesn't say who, it doesn't say what. Who's going in, in terms of position, it doesn't say what's going on, it doesn't -- you know, it might say free staffing, but it doesn't say, you know, is it just a random anesthesiologist who's going to be in the OR for the day --

THE COURT: For some reason --

MS. MAYER: -- for something else.

THE COURT: -- I jumped to the conclusion it was a nurse, but I don't know that it is a nurse.

MS. MAYER: Right, there's no information pled. So that's -- and that in and of itself demonstrates that the complaint fails to satisfy Rule 8 because it hasn't pled a violation. It's pled facts at a general level that depending on other facts might state a claim, but at the level at which they're pled are entirely consistent with legal conduct. Now, that doesn't mean that there couldn't be additional facts that flesh out theoretically and state an anti-kickback violation and remuneration, but it doesn't actually provide those facts, first.

Second, you raise the question of this is a motion to dismiss, isn't that a discovery question? How much do we expect a relator to be able to plead?

And I want to flag something for you. Ms. Forney, the relator here, started work at Medtronic in April 1996, according to her complaint. She joined the company and rose through the professional ranks, reaching the executive position of district service manager. So she was in the field organization. And she was terminated by Medtronic in 2012, supposedly in retaliation for her refusal to acquiesce in Medtronic's knowing and persistent violations of HIPAA, which we talk about elsewhere. She pleads that she has direct and independent knowledge of Medtronic's staffing kickbacks and HIPAA violations, and acquired this knowledge through her career of employment related to cardiac care.

So she is pleading, first of all, she was employed at the company for -- I'm not going to do the math correctly, but 16 years? And was in the field sales organization when she left. So during the relevant time period for this case she says she was in the field where the conduct was going on and she pleads that she has direct, independent personal knowledge of the staffing kickbacks.

So she is not a plaintiff who is saying, for example, I worked at Medtronic, I had no window into what Iver was doing or what Smith & Nephew was doing, right?

Sometimes you get a case where you have the plaintiff from one company who's then pleading more on information and belief about what maybe other codefendant companies are doing. This is not that case. She specifically says she saw it, so she is not someone who is incapable of pleading this.

Furthermore -- you know, so I submit that it's either she lacks facts that would support her claim and therefore she has pled at a general level, or she with consideration of counsel has made a strategic decision to hold facts back that would allow the Court to answer exactly the questions that the Court is asking. And we're now on a first amended complaint and the motion to dismiss and counsel has not to this point in the case offered what if any additional facts she would plead, if she were allowed to amend, that would enable the Court to assess whether remuneration that implicates the anti-kickback statute as opposed to free services or free staffing that is perfectly allowable occurred.

And I think in this case it's particularly of concern and why I don't think the Court should think that the cure is to allow amendment for two reasons. First of all, where she does offer a little more information other than just free services or free staffing about what the conduct was, she says it's either internal marketing strategy like Medtronic reps engaged in marketing strategic plans, which

obviously is not a service to anybody, or Medtronic developed patient relationships, which obviously isn't a free service to anyone. Or the free staffing and free services, she talks about troubleshooting, technical support, providing information about billing and reimbursement, all of this based on the AdvaMed Code, the pharma compliance guidance, the special fraud alert is perfectly acceptable.

She talks about Medtronic reps being present in clinics after implantation to help with medical procedures, checking on the devices. Well, that's just like the phlebotomist in the clinical laboratory guidance. As long as the technical and troubleshooting support that's being provided is to help the doctor and the doctor's staff appropriately use the product with a patient, it's not a free service or staffing that provides a kickback.

And so where she has pled facts that give a little more of a window into what she alleges is going on, they are facts that are consistent with legal conduct. And so from that, I think based on the fact that the Court has recognized there are critical questions that would require an answer in order to conclude that she has plausibly demonstrated that a violation occurred based on facts, and where she does plead facts, they go the other way, I think -- and that she's had already an opportunity to amend the complaint and has not proffered a proposed amended complaint suggesting in any way

that she could cure these defects in a way that would state a viable kickback claim, we think that with respect to the remuneration point, which I think is -- you know, is our lead argument, you know, is critical here.

And it's not in our reply brief and I apologize, but there are a couple cases in the Third Circuit that make crystal clear that if you want to amend a complaint, the courts expect that you'll supply a proposed amended complaint, so the court can evaluate it and, you know, the other side has a chance to evaluate it as well.

THE COURT: Well, free surgical support, what does that mean?

MS. MAYER: We don't know. It's free surgery --

THE COURT: Or implant device followup? Now, implant device followup certainly sounds like something that would be an appropriate free service if it's the manufacturer of the device following up on the success of the surgery and the success of the device as it's operating, it would seem, unless it's really just a way to put a staff member into the office that replaces another staff member that no longer has to be paid. And even that gets a little difficult, because in today's medical world some doctors are still independent, but it's becoming more and more rare, few doctors who are independent employ surgical staff, but the hospital does. When claims are put in, if the doctor is independent, he puts

an independent claim in to Medicare, the hospital would put its own claim in to Medicare. I'm not quite sure who puts the claim in for the device itself, I presume it's the doctor puts it in on behalf of the -- I don't even know, but in trying to determine what benefit, what substantial independent value went to the purchaser, and I'm assuming the purchaser here is the patient ultimately pays for it through Medicare. The doctor, is he getting a benefit from this surgical support? Is the hospital getting a benefit from free surgical support?

It gets very confusing to see just where the money is going into the pocket of somebody as a result of a false claim.

MS. MAYER: I think it's a fair question. I mean, we haven't briefed the reimbursement structure here, but the way in-patient care typically works under Medicare is there is a payment for the overall -- to the hospital for the overall in-patient care and the doctor may have his or her own, you know, entitlement to bill for services rendered. But, you know, if the surgery is performed in a hospital, the hospital is typically procuring the device. The physician may have say in whose device is used for which patient, so I don't want to suggest there's no opportunity for physicians to weigh in depending on the circumstances of the particular hospital and their arrangements with their staff. It may

also depend on whether the surgeon is employed or is a surgeon resident kind of practice with privileges to perform.

THE COURT: Well, you just raised a great question. Who decides it's going to be a Medtronic pacemaker?

MS. MAYER: Again, we don't have any allegations. And this is part of what we focused on it in the 9(b) context, but there is no connecting the dots. The focus of the pleading, to the extent it exists, is on alleging over and over again that there was this free service, free staffing allowed doctors to avoid, you know, paying for someone to do -- who otherwise would be paid to do the work, which we've explained isn't sufficient under Rule 8 to state a claim. But when you move to 9(b), it's crystal clear under False Claims Act that what is prohibited is not violating the anti-kickback statute, it's not, you know, doing any panoply of failure to comply with other regulations. All of those things only matter under the False Claims Act to the extent they result in false claims being submitted to a Government payer. False claims being submitted to a private payer, not a False Claims Act case. Violation of some really serious criminal statute? Not a violation unless that -- compliance with that statute --

THE COURT: Unless you certify as --

MS. MAYER: -- is required for submission of claims and submission of claims results.

Now, the anti-kickback statute was amended in 2010 and it says, if you fail to comply with it, you violate it, and false claims on Government payer results, that can state a False Claims Act claim. So there can be a connection, but you still have to plead both the entirety of an AKS violation, which is a knowing and willful violation, because this is a federal felony that for an individual could lead --

THE COURT: But that's what I was going to say. This is a criminal statute and you would expect there to be a bright line so that individuals and companies would know whether they are violating federal law or not violating federal law, and that's why that's more concerning than whether it's a False Claims Act. The whole idea that you could -- Medtronic could be violating a federal law, a criminal statute without even knowing it, because there's not a clear enough bright line about when it becomes criminal and when it is good marketing and good product service, et cetera.

MS. MAYER: Well, we think that in this particular case that is a particularly troubling and it has implications both for whether a violation has been pled at all, let alone with specificity, and also with respect to whether she has pled under Rule 8 a knowing and willful violation of the anti-kickback statute that then resulted in a knowing cause to be submitted a False Claims Act violation.

Here, where we don't even know what conduct actually, supposedly occurred. And we see clear evidence in the AdvaMed Code and in the pharma compliance guidance and in OIG fraud alerts advising the industry that product support services can occur as long as they are tied to a product that's been sold, that the kickback statute, that felony is implicated only if you're providing something that's independent of support for your product.

I think the key there is that the only way to hold someone -- that if you are going to then or argue that you've pled that a company has engaged in a knowing and willful violation of the anti-kickback statute by providing free services, at a minimum you have to plead facts -- facts -- that demonstrate that the company knew it was doing something unlawful when it was providing the services that you've described in your complaint. And there is nothing in this complaint that gives rise to -- that either pleads it or gives rise to any inference that the company knew it was doing anything unlawful.

The codes that I think the relator points to in this regard, we've gone through them. They don't -- there are general references to free services shouldn't be provided that could implicate the anti-kickback statute, but you can't read that without also reading the sections of those same documents that talk about how product support services or

other support services are permissible, right?

So when you're a company and you're trying to say, well, the company provided services, it knew it was committing a felony, you can't get there from documents that say don't provide -- you know, free services could implicate the kickback statute, but providing product support is okay.

Second, the relator points to -- it's a very convoluted argument in her opposition brief -- tries to argue that because the company was committing a HIPAA violation -- this is her argument -- using a Google Docs calendar program or Salesforce computer program, because the company at the highest levels company-wide knew it was committing HIPAA violations by using these software programs, well, that gets you to mens rea; that shows they knew that the patient information contained in that somehow represented kickbacks, and the company knew that they were illegal kickbacks because it knew it was engaged in a HIPAA violation.

So the logic here is so absent that I don't even know where to begin, but let me point out I guess three steps to why this doesn't get -- it doesn't provide any evidence of that the company knew it was engaged in illegal conduct when it supposedly provided the un-described free services.

First, the -- to the extent she is correct that the securities disclosure that she relies on for this admits, first of all, a HIPAA violation and, two, admits a HIPAA

violation related to Google Calendar and Salesforce.com. Even if when you read the securities violation you saw that, all that would be being admitted is a HIPAA violation, right? HIPAA regulates privacy, it says -- what it prohibits is not kickbacks, it prohibits the dissemination and inappropriately secured treatment of protected health information. So even if the company was admitting in a securities filing that Google Docs on some massive scale was violating HIPAA, it wouldn't have any relation to the anti-kickback statute mens rea that they need to plead here.

Second, in fact the securities violation that's supposedly admitted doesn't address Google Docs or Google Calendar at all. And, third, maybe most importantly, the admission of a HIPAA violation is not an admission of a HIPAA violation. I urge the Court to read the text of the disclosure. It actually says we think we're complying with HIPAA, we think we have adequate processes, but maybe there is risk and we're monitoring it, right?

Number one, this is a Medtronic-wide disclosure. To the extent they're saying anything about HIPAA, it could be about any one of a number of business units and subsidiaries. There is nothing that connects it even to the cardiac business division at issue in this case. There are other products that Medtronic manufactures that it also supplies to doctors and bills Medicare for itself. Insulin pumps is an

example of one where Medtronic is both the manufacturer and the durable medical equipment supplier. And so they -- Medtronic has records in that division of the company, patient medical records, the kind of stuff that's implicated by HIPAA.

So when it says we recognize we have HIPAA obligations, we think we're compliant, there's no basis for inferring that they're talking about Google Calendar, that they think there's anything wrong, and certainly not that they think that they have violated the anti-kickback statute by providing product support services in connection with the implanted cardiac defibrillators that they aren't a durable medical equipment supplier for. They simply manufacture them and sell them for doctors to implant and use in surgeries and then monitor in their own home, in their own offices, you know, as the label requires them to do subsequent to surgery.

So I think, you know, on the main -- I think we've touched on the main arguments, the 9(b) and then the two main Rule 8 arguments. But I'll say on Rule 9(b), and I do think it's important, the relator really tees up a strawman and then shoots it down in the opposition.

And I don't want the Court to lose sight of this: we never maintained in our brief and I don't maintain today that under Third Circuit law the relator is required to plead with specificity representative examples of false claims

submitted to Medicare in order to survive 9(b). There are circuits where you have to identify specific patient claims and information on those claims, those very specific claims, in order to survive a motion to dismiss.

The Third Circuit in Folia quite explicitly joined a few other circuits, including the First Circuit, the Fifth and the Ninth, that said that's one way of meeting 9(b), but another way of meeting 9(b) is to plead the scheme with particularity and to plead facts that demonstrate, that provide reliable indicia that claims were actually submitted that were false to the Medicaid/Medicare programs, to the Federal payers.

So it doesn't -- that means they don't have to plead details about representative examples, it also means that there are different ways to satisfy that standard. There's no one, you know, algorithm, you know, plead -- check the following six boxes to get past a motion to dismiss, but it means you have to plead facts demonstrating reliable indicia.

So what does that mean and why hasn't she done it here? In terms of the place to start, I think Folia is the right place to start. In Folia, first of all, a simpler theory of reliability. The issue that was up on appeal, the relator said vials of medicine, typically for a patient you only use part of the vial in a dose. If you bill as a single use, Medicare allows you to bill for the whole contents of

the vial. If you use it as a multi-use with multiple patient doses, you only bill Medicare for the amount you actually use. The theory was you're using it in a multi-use way, but you're billing it as if you're using it as a single-use vial. So you're over-billing Medicare.

The defendant was the medical provider and biller itself. So this wasn't a pharmaceutical company or medical device company engages in conduct that influences doctors' behavior over some subset of their patients and then maybe the doctor bills, this was -- the whole scheme was to over-bill Medicare for the use of these vials. And so the relator who worked at the billing defendant said we treated some Medicare patients, we do this across the board with them, and the company bills for it.

And that's not all. The relator also alleged based on inventory logs that for a specific month in October of 2008, by way of example, was able to allege on each day in that month how many vials were used, how many patients were seen, and therefore to demonstrate based on a reasonable inference you could draw from those facts that in fact the multi-use was occurring. That is way more specificity that we see in any piece of this complaint.

And then the court said that alone itself wasn't enough to deal with the reliable indicia problem, because they said, you know, in theory, they could have billed

properly for the multi-use vials, I know relator alleged they didn't, what else do I want to consider.

So then the court considered some additional allegations in the case and said there's really two scenarios that could occur here. On the first, the relator is right, Medicare is being billed, you know, for those multi-use vials, because they've established facts that, if true, plausibly demonstrate the multi-use, and that the bills were going out. Second, the court said the alternative theory is that because if you use it multi-use, there's a bunch of safety requirements you're supposed to follow, and the relator had alleged that those were systematically not followed.

So they said, so either they're over-billing Medicare as if this was single use or they're billing it as a multi-use and they're systematically not following the rules. So either way, we've got false claims, and that was what was enough in terms of reliable indicia. And the court said, wow, this is a close call; this is barely enough.

So here we have instead a situation where there is no pleading, first of all, that describes the conduct of the scheme. The conduct at issue we can't even identify really. You asked about what does surgical assistance mean. Well, surgical assistance, who knows what it means. I think critically, you know, as you said, if it's providing a nurse

to sit there and suture patients closed, that is not product support, but if it's to provide a rep in there to help the doctor program the device for the specific patient correctly, letting the doctor make medical judgments, that's not only product support, that's contemplated by the FDA approval for the product.

So, you know, surgical support needs to be explained in order to state a claim. What they've pled is entirely consistent with legal conduct and so there's none of the indicia that we saw in Folia.

And then second, unlike Folia where the court barely got comfortable because it saw only two alternative scenarios here, both of which led to false claims, here we have a whole panoply of scenarios open that clearly don't necessitate false claims. It's a more complicated case to plead in terms of steps, because you've got an anti-kickback-based False Claims Act claim that is a cause to be presented claims. So they've got to connect conduct by the manufacturer to doctor's decision-making to particular patients who are actually Medicare beneficiaries out in the world for whom claims were submitted. It doesn't mean you have to plead those individual claims with specificity, but you've got to connect those dots, and none of that happens.

And so is this fair? Well, you know, the courts recognize that this is a fair burden to require. She may not

be able to plead the doctor's own billing practices, but at a minimum she should be able to under the cases that we cite in the complaint.

And Rollo, which is a Third Circuit case, not in the False Claims Act context, that she cites as very consistent with this. We can talk about that, if it's helpful to the Court. But we've got a situation where, you know, under Hagerty, under Duxbury in the First Circuit, consistent with Folia in the Third Circuit, we're all doing the same reliable-indicia idea.

It's perfectly fair for a rep who in the sales force in particular at a medical device manufacturer who pleads first-hand knowledge of the conduct at issue to be able to say -- which included calling on doctors, right? -- to be able to say, you know, here are examples not just -- and here's what the conduct that clearly under the law and under the guidance shows it was a kickback, that the doctors as a result, they should be able to plead some facts that demonstrate that the doctors as a result treated Medicare patients, and then she needs to be able to allege that -- at least have a basis under Rule 11 to allege that those doctors then billed Medicare for those patients. That is not tantamount to pleading specific details about representative example false claims.

I think Duxbury itself is a great example of how

that worked. And the First Circuit agreed it was barely adequate, but it was a kickback case, it was a pharmaceutical company, and there you had the providers who received kickbacks identified. It was a monetary kickback in that case, so there was no question about whether she had pled remuneration or he had pled remuneration. So it identifies providers, it identifies the amounts of the kickbacks, the dates, and it alleges that bills were subsequently submitted.

In Hagerty v. Cyberonics, which is a more recent First Circuit case that has come out after Escobar -- and Escobar was not a 9(b) case, but it reemphasized how critical, you know, that the essence of a False Claims Act case is the claim and the misrepresentations in the claim. You know, in Escobar, you know, actual -- a lot of detail about the claims was actually pled and the claims process, and we don't have that here.

So ultimately, I think that clearly under Third Circuit law we're good. To the extent there are any District Court cases like Underwood that she relies heavily on that appear to be open to a more flexible pleading standard, I submit Underwood came out before Folia, so to the extent it's different from Folia, it's really not persuasive at this point.

I think it's also important -- and again, I don't want to overuse it, but I think it's important to recognize

Escobar was the Supreme Court speaking on an implied certification theory of False Claims Act liability, the first time they've addressed this ever. And if you read the decision, it's clear that 9(b) applies to every component of it, including the materiality of the misrepresentation of the claim, and you see the court very focused on the claim itself and what in the claim is false or rendered false by the noncompliance with the relevant statute.

And again, here we have the anti-kickback statute, I recognize it -- if you don't comply with the anti-kickback statute and that you're in violation of it and false claims -- and claims result that there is an FCA action, I don't think that's in dispute here, but the key is the claim is what triggers liability in the False Claims Act case, not a violation of the anti-kickback statute. You could bribe a doctor under the anti-kickback statute until the cows come home and you could be thrown in prison for that, okay? If that fraud is directed at the Federal health care program. But if that doctor doesn't actually submit claims to Medicare, you don't have an FCA violation.

And again, you don't have to plead representative examples of those claims, but you have to plead that connection. Otherwise, you just haven't pled FCA violation with specificity.

And I would say that this screen, which could feel

unfair, is an important one, because I want to tell you a little bit of the history of Duxbury, what happened afterwards.

So Duxbury was sort of the, you know, earthquake in pleading standards in the False Claims Act in the pharma and device world because it made it easier, it provided an alternative means to get to discovery, and the court allowed it and that case went to discovery. And it turned out that the defendant ultimately won summary judgment, because the plaintiff couldn't pony up evidence supporting the kickbacks that had been pled specifically in the complaint. So discovery was stayed until the First Circuit said this goes through. The district court decided to limit discovery in the first instance for the claims that had been pled with specificity and it turns out the relator couldn't prove them (indiscernible).

This -- yes, 9(b) serves an important purpose, because 9(b) puts defendants on notice of the details of a fraud scheme, but Rule 8 is about notice pleading. The other critical purpose of 9(b) is that it says that a fraud case can't go forward unless you can plead enough details to plead it with specificity; it serves as a screen. And in cases like this where the relators are whistleblowers, they're suing on behalf of the Government, but they have not themselves suffered any injury, right? I mean, Ms. Forney,

you know, is not someone who paid out money and suffered monetary loss herself because of the scheme alleged, she's suing on behalf of the Federal Government. Here, whistleblowers absolutely have a right to pursue these cases on behalf of the Federal Government, but there isn't the same sort of natural limit to their ability to pursue claims and try to pursue claims to incentive the Government to pursue claims that you have when the relator themself or the plaintiff themself has to suffer personal injury.

Now, the Government had a chance to look at this case and chose to pass on it. It does not give you a right to infer anything on the merits of the case because the Government can make that decision for any or no reason at all. However, I think the key is the relator is not the only person -- was not personally injured and isn't the only person that can go after this sort of stuff.

And so 9(b) in these kind of cases serves a really important purpose, because it can be easy for an unhappy employee to file a complaint based on supposition, speculation of possible misconduct and hand it off to DOJ, kind of like a tipster. That's part of what the False Claims Act wants to motivate people to do. It doesn't mean they actually have a good case, because, again, they weren't injured. What you have then is DOJ gets an opportunity to try to kick the tires on it and see if they think this is

really a problem. Or maybe they don't have -- like I said, I don't want you to infer too much from that, but I'm just saying that's structurally the way it works.

And so in these kinds of cases when the case comes back into litigation, I think it's -- it does the structure of the statute a disservice to take a particularly liberalized view of 9(b), viewing it as only a notice pleading statute, thinking that discovery is necessary to vindicate the Government's interest. Right? The Government has all sorts of tools that they could use to take discovery of defendants based on claims and either avail themselves on them or not, you know.

I'm not suggesting the False Claims Act here should get a standard of review that's different from Folia and Duxbury and Hagerty and what the courts have established the 9(b) standard is, but I think it's critical that you don't adopt a weaker version of that and if you allow this complaint to go through, you are diluting Folia, because they don't plead what Folia required and said was barely there.

The last things, I will just tee it up for you if you have questions on them. Otherwise, I know I've been talking a long time and Ms. Burke I'm sure has a hundred things to say in response, but we move to dismiss to the extent that there is any Stark issue here, because Medtronic is just a manufacturer, it's not a Stark -- there's no Stark

case here. We pointed out that the Stark law only applies in certain circumstances and laid it out in the brief.

One type of entity to which Stark could apply is something called a DME supplier and we pointed out that we're not a DME supplier here, we're not -- that's not -- this isn't DME. These are implanted cardiac defibrillator devices, it's not durable medical equipment under the Medicare standard for that that is supplied. Ms. Burke hasn't cited any case or any coverage decision or any authority establishing that these devices are DME, she has simply pointed to the definition of DME and said, hey, sounds like it applies.

The problem with that is the last critical piece to the definition of what constitutes DME -- and this is what I think most clearly takes this out of the realm -- is that it's appropriate for use in the home. So if you look at the DME coverage, the typical durable medical equipment are canes, wheelchairs, insulin pumps, bone growth stimulators, you know, external devices that you strap onto your body, that a patient can strap onto his body and then that a patient can use in the home. The only way these heart rhythm-regulating, internally implanted devices are used in the home is that a patient goes home and walks around and it's implanted in their body. That doesn't make it a for-use-in-the-home device. Otherwise, every medical device is

durable medical equipment and that's not the case.

And I think critically, you know, in the absence of some sort of evidence demonstrating that these surgically implanted devices that the patient never directly interacts with, right, the patient has to go back to the doctor's office to have it checked and investigated, that FDA is so concerned is used correctly that it built into the approvals that you need to get training and all that, it is not a for-use-in-home device, it's not -- you know, other for-use-in-home devices are, you know, Albuterol inhalers where the medicine is the Albuterol and you have a nebulizer. I have, you know, a child who needed a nebulizer for a short period of time. That's a use-in-home device. And a surgically implanted cardiac defibrillator that you have to go to the doctor's office to have the doctor interact with, check, adjust is not for use in the home.

So I'll leave it with that. I talked about the with-prejudice dismissal and the HIPAA stuff and --

THE COURT: And just the other thing about the state False Claims Acts. For the same reasons you believe the federal False Claims Act fails, but also I think the only allegation with respect to the state's is that it was a nationwide marketing scheme.

MS. MAYER: Yes. And I think --

THE COURT: I don't think there's any even mention

of the state.

MS. MAYER: Yeah. I think in the case with the state False Claims Act, these are causes of action under state law. So there's certainly a federal False Claims Act action under federal law, then there's -- you know, I'm just picking -- I don't mean to pick out Ohio, but way of example an Ohio False Claims Act count or a California False Claims Act count, if you walk into a state court in California, you have to plead conduct in California under 9(b) in order to survive dismissal, okay? If you're going to go into Ohio and plead a cause of -- say that the Ohio False Claims Act was violated, that only covers jurisdictionally conduct in Ohio or claims submitted to Ohio if the conduct was, you know, outside.

And so there needs to be some more pleading than just this conclusory here's what was done in this section of Pennsylvania and everybody did it the same way everywhere else kind of conclusory statement. And the cases support that, I think we cite them in the brief and so I'll refer you to the particular cases we cited. And she doesn't cite anything, any cases that hold otherwise, to the contrary.

Now, you know, are there cases out there that hold that you don't have to plead with specificity, you know, doctors and patients within Ohio in order for the Ohio False Claims Act count to succeed? Yes. However, in those cases

what you have is a massively more extensive pleading of the nationwide aspects of the scheme.

It can include things like, you know, relator went to national sales trainings every year from 2007 to 2010 and at those national sales trainings she was trained through role-playing exercises to go to doctor's offices and say, hi, I am here to offer to bring my nurse friend Susan to come in and do all of your nurse duties so that you don't have to hire an extra nurse for your routine patient care. I was trained to do that at all of my national sales meetings and we were told that this was our national sales strategy. Right?

If you have something like that and then you plead specifics, you know, I think courts have generally allowed those kind of state False Claims Act cases to come through. But here where you have to the extent any facts are pled at all with any specificity, they're all located only in Pennsylvania, which incidentally does not have a state False Claims Act, you don't get to then just say and it all happened nationwide too without any factual basis for concluding that this was a nationwide scheme.

She points to the use of her pleading in one paragraph of spare sentencing Google Docs and Google Calendar was used nationwide, but that doesn't do it. First, because, you know, it's so spare; second, because there's no

allegation that Google Docs and Google Calendar defined the conduct, somehow that this -- that if you peek into Google Docs we're going to see a description of the conduct. What it was was a patient calendaring program.

And the more fundamental problem with that is just like everything else that's alleged in the case, there are a host of reasons why a device manufacturer may want to have a calendar of patient visits to customers that are entirely innocuous and legal. For example, to provide post-implantation technical support or education or reimbursement assistance, to go to the doctor and help interrogate the device, to make sure that's being done correctly if the doctor has questions, right?

So the fact that there allegedly was a calendaring program that was used more broadly doesn't answer the question about, A, whether any inappropriate conduct was doing it, and it doesn't suggest that whatever the service was that was supposedly provided to the patient that was improper was nationwide, a nationwide scheme. It just says, nationwide they were keeping track of patients. It could easily, consistent with what's been pled, have a situation where one rogue rep and one district was doing something improper and everybody else was engaged in very innocuous activity.

And so what is absent or what you see in cases that

allows strong nationwide pleading to retain state False Claims Act counts in the absence of pleading conduct about in this particular state is strong facts pled that there was nationwide direction to engage in the precise misconduct where the court concludes, you know, if true, would constitute a violation of the False Claims Act.

THE COURT: Very well. Thank you very much.

Attorney Burke, I suspect you disagree.

MS. BURKE: Yes, your Honor. Do you mind if I approach the podium?

THE COURT: Not at all.

MS. BURKE: Thank you.

THE COURT: And would you agree that some of -- it is possible to take all of the facts and the conclusions in the complaint and still draw a conclusion that everything that the defendant did complied with the law?

MS. BURKE: No, your Honor, and really that is the nub of the issue before the Court. What the defendant has posited is that any services provided as long as they're connected to the product fall on the compliance side of the anti-kickback statute, but we know that's not the case.

Your Honor identified properly the troubling nature of the anti-kickback statute: it's broad and it encompasses a huge amount of conduct, and health care providers and corporations that are operating in the health care industry

are in fact being required to comply with something that's quite broad, but that is the reality of health care and those who participate in it know that they are obliged to scrutinize their own conduct and make sure that they do not cross from permissible to impermissible. And the crossover can be subtle, but it's a matter of degree.

For example, it may be appropriate and completely lawful for Medtronic to teach a doctor that's purchasing their device how to use it, how to train. The FDA contemplates that. Using sophisticated equipment, you need to be taught. Once that provider is taught, however, to simply keep sending another set of hands constantly we allege crosses over that line.

Similarly, there may be a time when the readouts, the data that's coming back from a patient is unusual or troubling, and a physician may have a need to pull in some technical support and say help us interpret this data. That's probably on the lawful side. What happened here and what we alleged in the complaint is -- crosses over into the unlawful side and that is to repeatedly, routinely, for regular-course-of-business readings have a Medtronic person do that work rather than the doctor's office.

So the crossing of the line is a very fact-based endeavor and determining the crossing of the line can't be judged in the abstract. What we've alleged, we say they've

crossed that line. We gave you examples of providers of the services, the dates that it was done. We also gave you examples of the rate it was being done, six, seven times a day just in one provider's office. So we've given you the sense of the pace, the sense of the scope, we think that crosses the line.

Now, obviously they have a right at trial to try to persuade a jury that it was all on the lawful side of the line and I don't begrudge them that, but that's a merits defense, that's not a pleading issue. What we're saying -- and our relator was in fact part of the company, she worked with -- she was someone sending out these reps and she's saying we sent them out for everything. That's exactly what the complaint spells out and it was done using Google Calendar and using Salesforce.

So we've given you a clear pathway to very easily and efficiently get your arms -- for us to get around and then show you here's the scope of this nationwide scheme. Here's the documents, they have the detail that is exactly what's needed to prove it up. They show the provider, they show what service was provided by Medtronic, they give us the patient name. And so the sheer volume of these free services being provided demonstrates the unlawful nature of it.

And I think that it's very important to understand that that issue, whether or not the in-kind re -- I have

trouble saying the word remuneration, but anyway whether --

THE COURT: It's funny you say that, because we were having trouble with that word earlier.

(Laughter.)

MS. BURKE: So I think that, you know, the nub of the case is are these services lawful or not. And the relator was part and parcel of providing these services, she was a participant in this unlawful scheme. She has put forth with personal knowledge and personal information the scope of the scheme, she's given examples of the scheme.

THE COURT: But when she would send people out, was it always for work related to the product?

MS. BURKE: Yes, yes. There's always -- it's always connected in some way to the Medtronic product, right? They are there because they are -- they sold the product or they're selling the product, and the whole panoply of services is in fact related to the product. That does not, however, give the bright line that it must be lawful.

And think of it in the same way as any other kickback in the health care field. For example, paying people to provide educational sessions, that's actually a lawful activity, but what happened in the health care field is that it's viewed then as a loophole and they drive a truck right through it. So suddenly they're giving way too much money consistently to physicians and then that is corrupting

their judgment and corrupting their purchasing patterns. It's the same thing here.

There is in fact a lawful zone of activity. It's lawful to help with sophisticated products when needed, it's lawful to provide some technical advice when there's trouble, but they've driven a truck right through it. What's not lawful is to day in, day out give an extra set of hands to do the task that the provider itself, that the physician's office should be doing.

For example, interrogating the devices, reading the data of people that have these, all of those are things that provider -- that the physician's offices are supposed to be doing as part of patient care. They love getting the free services, they love being able just to call up and say, hey, can you send a Medtronic rep down here to sit in my clinic for four hours? It frees up their staff, it gives them a real benefit.

So the question is not whether there's a permissible way to do it, the question is whether Medtronic drove a truck through that loophole -- not a loophole, drove through the line and provided it at such a quantum and such a degree that it's unlawful. And that is what the complaint alleges with specificity happened here.

Now, you know, obviously we would say the same thing 27 times. I tend to be very succinct, and you'll notice I

will be succinct here, I say it once and set it out there. It is complicated, but repeating it doesn't make it less complicated. So we're happy to answer any questions on it, but I think that I have properly pled all the elements.

THE COURT: I'll tell you where I have the problem, it is this issue of the lack of a bright line. So if there's a product and we all agree that you can send assistance out, technical assistance, et cetera, with respect to the product and that's permissible -- and you're talking about the quantity, but not just the quantity, but the quality of what's being done now -- when do you draw the line as to what -- and with specifics in this case, what was Medtronic doing where you believe it crossed the line, when the technical expert was doing something that didn't require a technical expert to interpret data, that it could have been done by someone else rather than a Medtronic employee? Like with as much specificity as you can tell me, when did they cross the line?

MS. BURKE: We think they crossed the line, as we pled in the complaint, they set this up as a way to market to providers, so they had the intent there to try to influence purchasing behavior. Okay? And we pled that. So they're promoting to the purchasers and they're trying to impact the purchasing decision by portraying themselves as this wonderful partner who will always be there at your side to

provide service. We think that shows the intent to cross the line, because it shows the intent to influence the purchasing decision.

In the world as it should be, the purchasing decisions are made without any freebies being offered and Medtronic only responds when asked to provide technical support. That's not what happened here. It was pitched to those who were making purchasing decisions, hey, listen, Medtronic is going to be there by your side. And the Google Calendars and the Salesforce calendar bear that out. We gave you a snippet in Pennsylvania, but this is a daily -- they created an entire network of people, of representatives out there in physician offices every single day. That whole nationwide scheme is what crosses the line.

And so I understand the complexity and the difficulty of looking at a case in which the law itself does not provide a bright line, but unfortunately the anti-kickback law does not.

THE COURT: Now, if they were providing all of this service and that had to be at some cost to Medtronics, hence the benefit to the purchaser. Were their products more expensive than a competing manufacturer who would not provide these services?

MS. BURKE: Yes, for example, in Europe where the products do not have this sales structure attached to it, the

Medtronic products are cheaper. So, yes, it does in fact, put into the cost of the product.

THE COURT: Now, I guess this isn't a big issue, but isn't it better for the patient to have this relationship with the manufacturer of a device?

MS. BURKE: No, your Honor. You know, just as the pharmaceutical manufacturers and others argued well, isn't it great that these doctors are all giving us education and that we're educating them? No, the reality is benefits, the money flow actually changes physicians' medical judgments. The OIG, in fact, the OIG sources that we've cited, point out oddly enough, you wouldn't necessarily think this, but oddly enough, even an inexpensive lunch will persuade a doctor to use a drug or use a device based on a feeling of friendship and the marketing works. And so, the provision of the free services has a negative effect on the health care industry because it induces purchasing based on something other than medical judgment about which is the best device.

THE COURT: I can't help but think of the analogy to buying some kind of technology with a computer. I buy a computer. Now, the Eastern District for the Northern Tier to have a computer person.

MS. BURKE: Mm-hmm.

THE COURT: But the manufacturer of the computer device would also provide customer service and

they'd constantly be available. So, when my computer's not working, I don't know how to work it. So, it's something very technical and it's complex, so I call for these assistance people and they're always available, always available. Now, does that save me having to have the computer person on my own dime? It does, but my own computer person couldn't possibly be trained adequately on this particular device unless he got training from my --

MS. BURKE: Well, that's the point, your Honor. The FDA requires that the company provide the training. So, these are, as we alleged in the Complaint. These are off-the-shelf products. We're not dealing with something new and fancy that hasn't been on the market. We're dealing with the commodity products. So, we're talking about physicians who have done this year in and year out. They've been trained. And what I would analogize it, sir, is for example, take you making a decision between using Lexus and using Westlaw. Lexus says to you, okay, here's our product and if you get in any trouble, you can call this number and we'll help you out.

Westlaw says, you know what, sir, we're going to provide people, associates to do the research for you. Please buy our product instead. There's a difference there and that's what we're dealing with. We're dealing with a promise and a provision of a level of service that influences purchasing decisions.

THE COURT: Of course, because that is very attractive to have that. That's a good thing. I mean, when you buy something, for a company to say we're going to give you A-plus service, we will always be available to you, except that that's a lot different than saying, we're going to come put the device in though, which would suggest with that research analogy. It's, here what they're saying is, we're going to be by your side. That we stand by our product and if there is a problem or you need technical assistance, we will be there, correct?

MS. BURKE: Well, no, it's more than that, your Honor. What it is saying to the doctor is, you know that kind of mundane task of checking on all of your patients who have these implantable devices that spit out all that data? You know that tedious task that consumes some of your nurses' time and your clinicians' time and is, you know, kind of tedious, but you have to do it as good patient care? Guess what, you're not going to have to worry about that. We'll give you that for free. Now, please buy our product rather than a competing one.

That level of free service crosses the line and you know, because it crosses the line, they shouldn't have done it. It was, in fact, a kickback and they knew, they knew from their own involvement in the reimbursement process and they knew from their familiarity with what the physicians had

to fill out on the CMS-1500. They knew that the claims for the purchases were being submitted and paid for by the Government. And because it's in this realm of health care being paid by the Government, it takes it out of what you and I would deal with and what we might think of as normal with computer support. So, promising, making promises to a decisionmaker, who is spending Government money, is looked at in a far different way than simply if you took the Government money out of there and you're just making a straight bid to try to persuade someone to buy your product.

THE COURT: Now, these cases are very interesting because of who the relator is and in this particular case, the relator was the person that was sending these people out?

MS. BURKE: That's correct. She was in management and she had worked there for almost 20 years. She worked across the country with all the other district managers. She became -- she was part of a task force that rolled out the sales force. She became upset with the company about the patient confidentiality. She was very concerned that this whole process of scheduling all these procedures was being done on a non-HIPAA compliant google tech.

THE COURT: And the reason it was scheduled with Medtronic was because Medtronic would send people out --

MS. BURKE: Mm-hmm.

THE COURT: -- with respect to each device.

MS. BURKE: Right and these schedules, your Honor, are the -- and they're voluminous, I mean, because each rep has many doctors and I mean, they provided the -- the quantum of services is voluminous. And these Google documents and these sales force documents, these calendars are going to be the key. This is going to be the evidence that proves to a jury that this crossed that line.

THE COURT: But what did they send us those photos of Google entry, that were going to Easton, Pennsylvania, Dr. Smith. Who are you sending to Dr. Smith?

MS. BURKE: Well, it's more specific than that and if you look at paragraph 25, it will say and we didn't put the patient names in the Complaint, obviously, for HIPAA reasons. But it will say who the patient is, what the procedure is or what the device is that they had in them and then what's going to be done. So, it is a road map to the free service that was provided. And so it will show you and we gave you that snippet of a few days in Pennsylvania, it will show you exactly the level of Medtronic activity across the nation.

THE COURT: Does that schedule show me who went there and what they did?

MS. BURKE: Yes, yes.

THE COURT: Because I did not see that. So, if I look at that Google, if I look at the Google spreadsheet and

that's what I'm supposed to draw from that, is what Medtronic was providing as far as service, free services to the physician?

MS. BURKE: Yes and if you look in paragraph 25, there's a listing there of what they did. And there is a complexity and we can certainly, if your Honor requires, we can certainly provide additional information, background information about what the service is. But Medtronic clearly, they're very familiar with these services. So, the way we've described it in the Complaint is meaningful to the defendant.

THE COURT: Now, what about the State Law claims?

MS. BURKE: The same, your Honor. This is not a situation that this was somehow a discrete, small scheme that was implemented just in Pennsylvania. As pled in the Complaint, the district that Ms. Forney worked in was doing the same thing as every other district. This is a nationwide practice.

THE COURT: Well, what I mean is if I pull up that Google spreadsheet, would I see an Ohio --

MS. BURKE: Yes, so basically, each district manager such as Ms. Forney, has say between two and ten people that work under them. And so, the scheduling is done at the district level. It's a way that the reps communicated with their management. So, it is, in a sense, like it's much like

having a taxi dispatch calendar. We know who was dispatched, where they went and what they did. So, those documents are the evidence and the road map of the scheme.

THE COURT: But, so I've got pacer check, I've got interrogation of device and device check. How does that tell me that what they're sending out is not consistent with product service?

MS. BURKE: Your Honor, in any -- the reason is --

THE COURT: Not to interrupt you, but --

MS. BURKE: Yes.

THE COURT: -- because I was looking at this, I was thinking, all right, how do you save a doctor money? And I was thinking you give him somebody that he wouldn't otherwise need.

MS. BURKE: Yeah.

THE COURT: Or you give him somebody that he otherwise would need, so he doesn't have to pay that person. Because then again, it is things about hospitals and who's paying who and whatever. How does the fact that Medtronics did a pacer check help the doctor, other than the fact that he's making sure the device works properly so his patient doesn't die.

MS. BURKE: It basically eliminates the doctor needing to do the pacer check or the doctor's staff person needing to do the pacer check, a clinician paid by the doctor

to do that check. So, all of these services that are done are things that need to be done, presumably. So, the doctor is, when a doctor implants a device, a doctor is supposed to check on that device. They're supposed to make -- they have certain standards of practice where they routinely check in on these devices. But for the free people that Medtronic was providing, the doctor would have to get that task covered in some other way. And so, all of the services that are being provided, the quantum of services, is the proof that it crosses the line.

Any single service in isolation, if this happened just once, there might be an argument that it was permissible. So, you have to look at the totality of what Medtronic was providing. Because it is that totality of the services and the marketing that goes along with it, that demonstrates, that will serve as the evidence to demonstrate to the jury that it crosses the line into illegality.

THE COURT: Okay.

MS. BURKE: Your Honor, I really think that the question of whether or not it's a kickback, obviously, is the key question. I don't think it's appropriate for your Honor to decide that without evidence and without discovery. So, we would ask that the case move forward.

From my perspective, we believe we've properly pled anything. If you disagree, obviously, I'm happy to plead any

other facts that you want, because this is a person who worked for the company for almost 20 years and the full, you know, the full quantum of her knowledge is, I mean, we can provide additional details about what an interrogation is and we can provide additional details about anything that your Honor views as appropriate. We do believe --

THE COURT: Well, no, what would be interesting is if somebody has technical knowledge. Like if you say, they sent out a salesperson to do a pacer check just so the doctor didn't have to do it, that's a little different than we've got a technician who is a specialist in our device and they are sent out to do it and that would be somebody that a doctor normally wouldn't have, an expert technician in this particular device. You've suggested it could just be a, I think you've been suggesting that a lot of these jobs, responsibilities, et cetera, could be done by anybody or just a normal medical person, they don't need a technical professional from Medtronics to do it.

MS. BURKE: That's correct, your Honor. And that's why we specifically pled these are not new technologies. These are off-the-shelf products. There are devices that are well used and well known. So, we're not -- although they are sophisticated devices, the routine interrogations, the routine checking, it's not something that a clinician cannot do. In fact, the physicians -- the FDA tells Medtronic, make

sure you train other people to do that and they say train them. They don't say do it for them. So, the FDA approval itself makes sure that Medtronic doesn't keep a monopoly on this type of ability to service these products.

THE COURT: So, if I brought in the cardiologist involved here and I said could you have done this, made this device check on your own? Did you need to use Medtronics, the cardiologist would say yeah, I could have done it on my own?

MS. BURKE: Yeah, I know how to do it, correct. Or you now, Ms. Smith on my staff, yes. You know, when we can't get a Medtronic rep out here, Ms. Smith does those checks.

THE COURT: Okay, so the question is to what extent is this just good marketing and good support and to what extent is it a bribe or a kickback?

MS. BURKE: Well, bribes can be good marketing, right?

THE COURT: Absolutely.

MS. BURKE: I mean, this was very effective marketing. So, it's effective marketing and it has a ring of legitimacy that, you know, we care about our product, we're going to educate you on your product. But I would encourage your Honor to remember we have to think about this not in a normal business practice sense, but when you know the purchasing decisionmaker is not spending their own money.

They are buying a product using Government money. So, when you are looking at why this type of free service had a corrupting affect on the purchaser, it's because the Medicare and the Medicaid program don't benefit by this benefit. The upside of all of that service doesn't flow to the Government. It flows directly to the physician and the hospitals who can keep their overheads lower. And so, you know, those overheads are not -- hospital reimbursement, obviously, is a little more complex, but overhead in general, is not reimbursed by Government money. So, that's the area where the physicians have the incentive to try to keep it low. That's why an extra pair of hands, that's why a Medtronic representative sitting in their clinic and entering, you know, data check, data check, data check, eight, you know, okay, they tick that box for all those patients. That saves the physicians overhead.

THE COURT: Now, the people your client was sending out, you use the term sales representatives, did she send out people other than sales representatives to these different doctors offices? And were sales representatives doing these pacer checks and interrogation of device checks?

MS. BURKE: These were people that had undergone training by Medtronic. So, they were knowledgeable about the devices and they were knowledgeable about the product. So, it's not akin to a sales rep who knows nothing about a

product.

THE COURT: But was her official title sales rep?

MS. BURKE: And I, I'm sorry, your Honor. I believe that they had a different, I think it was called service, service representatives. Although, your Honor, I apologize, I want to make sure that I've got that terminology right.

THE COURT: Oh, that's okay.

MS. BURKE: So, I'll put that in, in paper, if you don't mind.

THE COURT: Did they both sell the device and service the device?

MS. BURKE: There were other organizations that just sold the devices, so they would work king of hand in hand together. So, there was a whole service district management -- district structure. So, what Ms. Forney oversaw were people who were just providing these services, not just the initial sales of the device.

THE COURT: Okay, so she actually oversaw that people that were the service people?

MS. BURKE: Exactly.

THE COURT: Not the sales people?

MS. BURKE: Correct.

THE COURT: But what was her actual title, if you recall?

MS. BURKE: It was District Manager.

THE COURT: Okay. And I think it was actually for the Eastern District of Pennsylvania, wasn't it?

MS. BURKE: That's correct, your Honor, yes.

THE COURT: All right, thank you very much.

MS. BURKE: Thank you.

THE COURT: Counsel, would you like to respond and what about this argument of the proof is in the quantum as opposed to the specific quality of the service for the specific service, that there's so much service -- so many services being provided that the quantum demonstrates that this is going above the pale and is actually an unacceptable kickback in the form of staffing services?

MS. MAYER: I think that and you know, I appreciate her candor with the Court here. I think first I'd like to put the focus very clearly on something that she agreed with and that appears no longer to be in dispute. Which is that the services that are at issue here, the free services and the free staffing --

THE COURT: Are related to the product.

MS. MAYER: Are connected to the product and in and of themselves, beside the quantum, perfectly legal, okay. So, what Medtronics was sending its people out to do, we all agree apparently and I didn't know exactly what she was maintaining it was. And now she is saying, yeah, it was on its own, put aside the quantity offered, fine, legal. That's

not an issue, so she allows them in to complain, to describe in more detail what's going on. She agrees she's not going to be describing something that doesn't fall within permissible product support services.

So, now she's saying what this case is really hinging on is this entirely novel theory which is unanchored in any case, guidance, industry standard, that somehow providing product support services is permissible. But only up to some undefined account that can't be articulated and the Court can't decide, we have to give it to a jury after full discovery and a trial.

I submit you can't say that a line between felony and perfectly legal conduct, when we all agree that the conduct you saw as legal, is something that cannot be ascertained as a matter of law. And again, in order to say that if the quantum of it is what makes it a kickback, you have to be able to point to law that establishes that fact.

She analogizes to physicians with her program and that's an inapposite analogy. First of all, physician speaker programs are something that companies have done. It is allowable under the anti-kickback. This situation, this is not product support. This is where you enter -- a physician is paid money or for time to teach and promote the product, okay. So, because paying a doctor to promote the product is offering remuneration, something of value that's

recognized to not be product support, you could only do it if you structure that relationship in a way that fits within the safe harbour of the anti-kickback statute.

And so what companies do is they enter into a contract. They set out this compensation and stamps and get fair market value opinions or analysis. There's a whole industry that generates fair market value analysis for the physicians' time and effort in connection with those speaking programs. If physician is paid a fair market value for speaking under a contract, you can do that. You can do it for one physician and you can do it for 3,000 physicians. There are pharmaceutical companies that have speaker bureaus with 10,000 physicians and that's fine, as long as they're paying them fair market value and there is a commercially reasonable basis for doing that number of speaker parts. If you pay someone to speak over and over again to the same three doctors on the same topic, right, you're going to have some trouble.

But if you pay that same doctor over and over again to speak to five people in different places around the country who haven't heard it before, fine, that's kind of common sense. These are not complicated, long lines to drop and most critically, there are cases, guidance and fraud alerts and DOJ settlements that all layout the ground rules in this area. Here, there is nothing, other than Herrick

(ph), which is a case that we cite. That's a District Court decision in Pennsylvania that recognizes that it's not enough to argue that free services are provided, you've got to go in detail and prove there are actual remuneration. Here, she doesn't have an answer to how you decide how many times Medtronics can be at a doctors office before it goes from being a permissible level of product support to kickback.

I want to address just a couple of other things that she said. First of all, I think you asked her if, you know, she emphasized that the proof that she would put in front of a jury of the fact that this was a kickback is not, you know, she wouldn't be able to ask you to write jury instruction based on the law. She's going to say that the proof is that Medtronic marketed these product support services as something that should be taken into account by doctors when choosing Medtronic's product. Well, of course, permissible product support services are permissible to market, just like if your device has a technical advantage, you can tout that technical advantage when selling your device. If you are taking on the expense of providing stellar product support that is legal, you can tout that to market it and it is not evidence that you're trying to bribe doctors to buy product. You're trying to convince them to buy your product by having a permissible aspect of the product provided to them in this case. These are product support, which we agree all of us,

with what was being provided.

So, how do you get to the point where you're providing too much product support is a kickback? Well, you don't, as long as the actual product support was for legal purposes. And I mean, she says that whereas Medtronic was doing in product support is something that the doctor would otherwise have had to pay someone to do. Again, that's not the question here on its own. That establishes that there was a value to the product support, but we -- that's not really in dispute. It's a valuable thing.

The question is, it has to have value and be independent of the product before it's implicated in the kickback statute. So, for example, if you provide product support in the physician's office, that's fine. But if you then offer a reimbursement guarantee, this is something we see sometimes in the cases. Product support is fine. Reimbursement advice is fine, but if you then say, you know what, if you try to bill for this to Medicare and they refuse you, I'll refund the cost of the product. That is not product support. That's something that's in addition.

There is case law. If there was no case law on it, it might be an open question. There's no case law saying that if you provide permissible product support, but too much of it, it's a kickback. And I think that the key here is whether you issue a decision that finds that they haven't

pled adequately and can't fix this under the definition of remuneration or not, what's crystal clear from this argument, I think, is that she can't and she hasn't and she can't plead knowledge. Because and the requisite mens rea under the anti-kickback statute, because when you look at the anti-kickback statute, when you look at the guidance on it and you look at the case law on it and there is nothing that suggests that if you're otherwise providing permissible product support services and staffing, that if you provide too much of that, that that's when you cross the line. The discussions -- yes?

THE COURT: Well, the analogy that she used was this idea of there is the loophole and you referred to it as a loophole, but this idea that this is legal, this is not violating the anti-kickback and then drove a truck through it. Now, I can see -- I don't know that Attorney Burke is fully conceding that all of this was product support. But let's assume that she is. I could see issues where it could be difficult to tell. Like, suppose you have to have an operation to have this put in and you have sutures and they send somebody to check on your sutures. That doesn't seem to be really related to the product, even though the sutures were a result of having to put the product in. All of these seem to go directly to the device. I only have a list of them here, but they're pacer check. If it had been wound

check, that might be a little more questionable whether that's truly product support.

Interrogation of the device, that seems clear from what I can tell. Interrogation of the device seems it's the device. Pacer check, device check. But so, if Attorney Burke is conceding that, any one of these standing alone would be okay. But they're going above and beyond providing support that's really not necessary. It's yes, it has related to the product, but it's more support than you would ever reasonably consider to be reasonable. What if that was the argument, that this is support that goes beyond the pale.

MS. MAYER: So, I think the challenge there is if that's the theory, you need first of all, if it's not for the -- but even assuming that part of this exercise is to evaluate whether she could, in theory, have a Complaint to plead something that was viable. I think the challenge there is there's nothing -- no, what she has alleged is that for any -- what she is saying in argument is that if you look at the level of any individual patient, you know, what Medtronic is doing is, you've got a schedule of the procedures that's going to be done on the patient and then sending someone there, okay.

You're saying well, surely for some of these procedures for some of these patients, maybe it's sufficiently routine that Medtronic wouldn't have needed to

do it. Okay. Assuming that's the case, what that means is that you can't just pull six patients off of Google calendar and say, these are examples that help to explain that the legal procedures were being done because of these particular patients, any procedure is, you know, this might have been an incredibly -- even just buying into the theory for the moment -- an incredibly complex procedure was appropriate.

I think more to the point, if this is permissible product support, which we think they'll all generally be in agreement on, the fact that a doctor maybe could have done it as well or could have done it in tandem with the Medtronic person, it's still permissible product support and you're entitled to this. It's an expense Medtronic can take on and if allowed to market that as a reason to use its product.

I think one thing I wanted to address was the cost issue because you raised it. I think we need to keep and I'm not sure if it's clear enough. The doctors are not buying these devices and then billing the device to Medicare. When the devices are acquired and implanted surgically at a hospital, so the cost of the device itself is a cost that the hospital incurs and that's not a cost that's capped on directly or billed directly as a line item to Medicare. Surgeries are reimbursed under a code, a diagnosis code that encompasses the overall procedure. So, whatever device is used and some are more expensive than others, the Medicare

reimbursement is the same. The hospital may incur more cost if they got a more expensive device. But I just want to make clear that the cost went to Medicare, service is done later in the physician office with respect to checking the device and other things. That doesn't mean you're buying the device and billing for it at that outpatient setting. There may be service codes billed if the doctor performs a service that's billable. But there isn't the cost of the device. I know it's something that we've talked about a few times here, is not something that's being passed on to Medicare. It's not like pharmaceutical products that, you know, Medicare might reimburse for pharmaceutical products at average sale price plus a percentage or something like that. This is an in-patient surgery. The surgery is paid at the same rate regardless of the plan.

THE COURT: I keep thinking about this idea that we have a relator who was in the middle of all of this. So, she knows what was going on and she believes wrongdoing occurred. And she was actually the person sending out these service technicians or service people, whatever it was. And in her mind, she was thinking, clearly if the doctor called up and said hey, I want some, can you get me lunch. And they sent somebody out to get him lunch, I would think that would not be product related, even if he was about to do surgery and he was hungry. It wouldn't be product related and that would be

-- violate the kickback statute. It wouldn't be within this what's referred to as a loophole.

She knows what was going on and she knows she was sending these people out and she believes she was sending too many people out or she wouldn't have brought this lawsuit. And the question is why she believes that. Because if it were not related to the product, clearly we would understand why she would believe that, just send somebody out to get lunch. If she's sending people out more than she believes she should be, that this is padding the doctor somehow. This is giving a benefit to the doctor beyond what is reasonable and I think as best it's been explained by Attorney Burke is this idea that the nurse would have to do this check and if we send this person in all the time, then the nurse doesn't have to do this check. I think that's the argument.

And so, I think from here standpoint, it was that and now I'm just trying to put this together, is we were sending too many people out for too many things beyond what needed this technical expertise. Is that how you read the Complaint?

MS. MAYER: That's how I read what Ms. Burke is saying the theory of the case is. The Complaint is nowhere near that that clear and doesn't plead those facts. We've gone way, just in the course of today, to be crystal clear, we've gone way beyond what's actually alleged in the

Complaint. The Complaint doesn't allege that these are even services that Medtronic provides as opposed to simply a calendar of procedures the patient was to have. They do not allege that no doctor was going to be present or that no nurse was going to be present, if that's even true and if Ms. Forney even knows, which she might not for these specific procedure. There is no allegation there as to any of what Ms. Burke has now framed as the theory that's driving the Complaint.

I think, but again, she has asked for leave to amend, so I think it's productive to have this discussion to probe what she would plead if she were allowed leave to amend to try to fix the Complaint. And I think the problem is, we still get back to this, under Bell Atlantic v. Twombley & Iqbal, it is crystal clear that the Court is not to defer, in any way, to legal conclusions alleged in a Complaint.

You ask me, well, Ms. Forney believed that she was sending out an unreasonable number of people. She is drawing a legal conclusion. If she reframed her Complaint to allege that it violated the anti-kickback statute to send out too many people, that would clarify the Complaint that that is a classic legal conclusion that is entitled to zero deference. And that must be supported by law, regulation, guidance, some authority other than Ms. Burke or Ms. Forney's say-so. It's not a factual question whether too much product support turns

permissible conduct into a felony that can subject individuals to 20 years in prison. That can subject a manufacturer to permanent exclusion from federal health care programs. This is not a technical football that we're talking about here and there is no authority that Ms. Burke has offered in her opposition whatsoever that supports this notion that if you provide permissible product support, but do too much of it, whatever that too much of it might be, which she cannot articulate, that you violate the anti-kickback statute.

And the complete legal support for this proposition connected with the fact that there's guidance that says product support is fine, as long as it falls into this type of category. And those categories and describers in the guidance documents do not say but be careful you don't provide too much of it. There is, again, if you're not inclined to rule on the question of whether her theory is based on remuneration, it's crystal clear that there is no basis for something that Medtronic somehow knew that after providing x-amount of product support, it had crossed the line into product support.

And we haven't talked about this yet and I do want to mention this one thing that she sort of flagged in her opposition and it's important. Is she said in argument that, well, the anti-kickback statute can be confusing, but gosh

darn it, you know, health care companies know they need to be careful in this area and in parsing. Okay, great. So, she suggests Medtronic should have gotten an opinion from OIG, giving them an answer to what they're to do here. First of all, we'd cite the case, it is 100 percent inadmissible to use the failure to get an OIG opinion as evidence to support a theory that you violated the anti-kickback statute. So, that argument is out.

But then let's take a step back and say, well, if Medtronic was supposed to ask itself the question, since Forney had raised the issue with her supervisor and said, I think we're providing too much product support. You know, some is fine, but we're crossing the line. How would Medtronic have evaluated what that line should be, right? They'd be looking at the exact same stuff that we've put before the Court and there is no answer in it that says here's how much -- here's what too much product support would be.

And again, what Ms. Burke should continually come back and I think it's been part of the discussion, is oh, well, one way to conceptualize it is, is the doctor getting a benefit here. Is this a service that their nurse would have done? And again, what is so critical here is that you can't have that discussion until after you've determined that this falls outside of product support. Because product support,

by its nature, saves the person receiving the benefit of it, money, time, effort, staff, whatever. That just comes with the territory. If I give a doctor reimbursement advice, he doesn't have to have his nurse spend ten minutes for every claim looking up that reimbursement advice. That's money in the doctor's pocket, but it doesn't implicate the anti-kickback statute. That's not the test because it's product support. If I help the patient with prior authorization and dealing with the reimbursement services, that saves the doctor a lot of time and effort because they don't have to have someone in the office walking the patients through that process. But a manufacturer can do that as product support.

I can collaborate with the doctor and provide form letters and help the doctor advocate for coverage for my products. If I don't do that, the doctor would have to do that himself. That saves him or her time, money, effort. It doesn't matter. That is not the test for whether product support turns into a kickback. Because first, if it's product support, it has a value. You can market product support as a valuable benefit because it's not remuneration under the anti-kickback laws.

THE COURT: Now, is it fair to assume that Medtronic still provides this product support at the same level that it always have?

MS. MAYER: I have not inquired of my client of that

in particular, so I can't speak to that.

THE COURT: And what do you think if they filed requesting an OIG advisory opinion as to there marketing plan? What would happen?

MS. MAYER: So, again, I think it's a fine question. I think one thing that needs to bearing in mind is the OIG is not obliged to respond and provide an advisory opinion one way or the other or at all. And there are plenty -- it is outside the scope of the Complaint and the briefing, but you know, many health care colleagues periodically do seek advisory opinions on behalf of clients and sometimes, you just don't get an answer. You don't get an answer for five or six years. It's not as though this is a process where any health care provider or company can issue a request or an opinion and within 30 days they get a clear response back. There are host of reasons why we might or might not and that's why it's critical that there is no and then not a case that directly holds, there was just in the statute itself provides. This is a voluntary process that you're counting your patients. But it is, you can't draw any negative inferences from it or abuse it in any way to suggest that there's been a violation if you fail to follow that there are relative to the number of questions that are out there in the full scope of the health care industry. The OIG advisory opinions, volume, is like Supreme Court decisions compared to

District Court cases. It's a limited resources that OIG have and they don't, you know, not everybody asks and they don't respond to everything and it is, you know, it is perfectly acceptable and normal. If everybody has to ask for an opinion to bless a marketing issue, you now, OIG wouldn't be able to handle the volume.

THE COURT: Okay. And Attorney Burke, if the -- first of all, are you satisfied that the focus of your claim and of Ms. Forney's claim is not the type of support that was being provided, but the volume of the support?

MS. BURKE: Your Honor, it's a bit more than that. Counsel acts as if there is permissible product support that is legally supported. That's actually not the case. There's no a safe harbor. If you look at the text of the anti-kickback statute on page 12, it's clear that this is, in fact, an in kind payment to induce a purchase. So, definitionally, it appears to be a kickback. Now, because the kickback statute is broad, the OIG and Congress have carved out safe harbors. If this practice was, in fact, a commonplace and nationally accepted practice, it would be protected by a safe harbor. There's no safe harbor that protects this. Nor is there any OIG advisory opinion that protects this. And in fact, the only thing that defense counsel was able to point to was an industry code. And even that code has some language that helps us. So, it's an

exaggeration to act as if we have some kind of legal safe ground for product support. We don't.

Now, personally, I believe that one could argue and I was a defense attorney for the health care industries for years. So, it may be kind of that bias and in fact, I was counsel -- defense counsel in the Dacksberry (ph) case. I believe it's probably -- there's probably an argument to be made that a certain amount of support is necessary at the initial purchase of a new product. And there, you get into the FDA approval saying, go ahead and train the physicians. So, we're not going to take the position that any and all, even you know, one visit would be illegal. We think there's probably some small amount of training, some initial for new product that's coming out, there's going to be a period where it's more appropriate.

So, but it shouldn't be flipped as if somehow we're not proving that there's case law to prove it's illegal. The statute itself makes it illegal. And then I would also cite, your Honor, to the very important Berber (ph) case, which says okay, we're going to have to look at motivation. Why are they doing this? And that's where, as we've pled, it was a marketing scheme. And if one purpose is to impact the decisionmakers, then you've crossed over into anti-kickbacks. So, I think it's clear from the Complaint and from what we've pled, that we're dealing with a situation where there are a

series of de facto kickbacks. And so, I think that this notion that somehow we haven't come forward with law or case law is simply wrong.

I would also suggest in the health care industry, every single one of the things that has been found to be a prohibited kickback was initially argued by industry not to be. So, you know, if you go back 15 years, you'll see it's always a developmental thing. And in this particular area, Medtronic has a lot of experience because in Massachusetts, in the Witkin case, on very similar facts, they're already under discovery and the case is already proceeding on a very similar theory to here, albeit, in their diabetes product.

So, it is simply wrong to suggest that we don't have the law on our side. We have the law on our side. The only thing at issue for you and for the jury, are what are the facts? Was it as we say, a widespread scheme that went out and provided all these services. We have to prove that up, obviously. So, I think that -- and your Honor, just to clarify, I'm only asking for leave to amend if you find deficiencies. I'm not, in the abstract, asking for leave to amend. I was very careful and think I hit every mark. I gave specific examples. We pled that it was for off-the-shelf commodity products. We expressly pled that the marketing was aimed to change to impact the purchasers. And we made it clear that hospitals are one of the purchasing

categories.

So, I think when you go through the Complaint and we laid it all out in the opposition brief, that we have hit everything that needs to be alleged and we're alleging it with personal knowledge of Ms. Forney, who was an executive for Medtronic.

THE COURT: Thank you.

MS. BURKE: Thank you.

THE COURT: Counselor?

MS. MAYER: Your Honor --

THE COURT: This is all very, very interesting I find.

MS. MAYER: I find it wonderful that you're so engaged and happy that you have questions that helps us make sure we're addressing what is on your mind.

In terms of this argument that product support is a kickback, because it plainly falls within the anti-kickback statute. The anti-kickback statute prohibits offering remuneration in order to induce a purchase. So, first you have to show that this is remuneration. In-kind gifts can be remuneration. The purpose of the HHS OIG, the people that wrote the safe harbors. The HHS OIG pharmaceutical compliance guidance, which says that product support services are fine as long as what they are, are tied to the product and they're not providing an independent -- substantial

independent value.

And the Advamed (ph) code, the reason why the Advamed code, you know, these are documents from 1994, from 2003 through 2009, that neither DOJ nor HHS OIG or anybody has ever jumped up and down and said you're wrong. Client support services are absolutely a kickback under the anti-kickback statute. You have to fit within a safe harbor. You have to go get in it. Nobody has ever said that. She points to no authority that suggested anyone's ever pushed back against this advice from the pertinent regulators saying it's not remuneration if it's product support.

So, the reason why this doesn't fall within the anti-kickback statute is you don't even get into this gate, because product support services don't provide a substantial independent value that would then potentially trigger. What would be an example of an in-kind kickback, I think you've given some today. Medtronic was sending reps, not for pacer checks, but for wound care cleaning, right? That would be an in-kind service that's of value and independent of the product, right?

So, then that's also in the ambit of the in-kind, you know, product that falls within the anti-kickback statute, because you first determine that it's not product support that falls outside of remuneration according to the guidance. And again, I can't emphasize enough and I

don't think she has an answer to it, even if you are intrigued by her idea or hesitant to rule definitively one way or the other that product support services, especially on those first allegations here, do not constitute a kickback. I think we've given you more than enough to rule that she hasn't pled enough and that her burden here to establish that there's been a violation there.

From a knowledge perspective, there is no way, based on the guidance that we talked about today and they were cited in these briefs, that Medtronic would have any basis for believing that it should disregard what OIG -- HHS-OIG and Advamed are saying is entirely permissible conduct when it's connected to the product you're selling, which we all can see is what's been going on here.

In terms of the Massachusetts case that she cited, where she says Medtronic, of course, knew that product support services were a problem. There are two things that I'd like to cite on that and I'm intimately familiar with the case and I am defense counsel for Medtronic in that, as well, for full disclosure.

First, the motion to dismiss in that case which allowed a portion of the Complaint to go through, found it was sufficiently pled, came down in 2016. So, for purposes of the conduct at issue here, it's not as though Medtronic had a judicial decision, first of all, even assuming that the

decision is pertinent here. There was no judicial decision endorsing anything like the notion that product support services could be kickbacks, that was in place during the time period that's at issue here in this case, because of it's relevance here for knowledge for any account.

Second, in terms of arguing that what was pled in Witkin is the same both in level of detail and in theory as what's been pled here, that's simply not true. The critical difference is Witkin was several pages of pleadings generating detail of alleging that, in that case, that sales reps were going into doctors' offices and having doctors line up patients where Medtronic would put on a medical device that was a clinical thing to do. And then send the patient off and the doctors would bill for this medical service to the federal health care program.

So, first of all, we don't have an allegation here that Medtronic did so and so and it is beyond product support and it was replacing medical care. What the argument there and that Medtronic was instructing doctors to bill for the work Medtronic did and that Medtronic full well knew doctors were billing for the work that Medtronic did. And so -- and so that's just a theory, which is very different from what we talked about here. And then second, what is critically different is that the degree of specificity with which that theory was pled is not just three dozen paragraphs providing

details providing examples of doctors, but the relator also appended, as an exhibit, examples of actual false claims. And so, the notion that because this case got through the motion to dismiss on those theories has either teaches Medtronic that what she alleges was going on, on the cardiac side, was a kickback in any way that's relevant to this case, doesn't work from a timing perspective and it also, it is materially different from a level of pleading perspective. And she has not suggested that she would be able satisfy the pleading standard that the Court held of the plaintiff in the Witkin case.

THE COURT: Now, would it make a difference to you if, let's just use the instance on page 8, would it make a difference to you if each one of these things, the pacer check, device check, the interrogation of device, if each one of those was done by somebody by Medtronic, that the doctor then billed Medicare for it?

MS. MAYER: Yes, if that's what she alleged, I think that might make a difference here. It's not what's alleged and that isn't the theory that she's articulating here and I would also like to point out that they don't even allege in the Complaint that these examples were billed to Medicare or that these were Medicare beneficiaries.

THE COURT: Right.

MS. MAYER: So, just for purposes of this. But if

the device and the general principles, the device company performs a clinical service, you know, if you're not a clinician, that's its own issue. But -- and the doctor bills for it, if the device company caught the doctor bill for it, I mean, right? Then the device, that would be a problem. I would say, you know, doctors are allowed now to understand doctors might be able to bill for -- if they exercise a supervisory or in the billings complex. This is why -- I don't mean to be hedging in a bad way, but I'm just saying doctors are allowed to bill provided they exercise sufficient, often supervision over somebody else performing the service. If that person was a nurse, that's great. If that person was Medtronic, that's fine, as long as the doctor provided the appropriate supervisory role and met the requirements for billing. It doesn't necessarily matter who the lower-level person is, as long as they have a relevant clinical, you know, bonafide.

I think the key here is that the whole -- that is not at issue, so I just --

THE COURT: But isn't that more of the issue of Massachusetts, the idea that Medtronic provided this clinic that provided the services that really had very little to do with the doctor and the doctor had billed for?

MS. MAYER: So, at the pleading stage, that was what was pled. You will not be shocked to hear that, you know, we

have a very different view of the facts of the case and are looking forward to an opportunity to vindicate ourselves.

THE COURT: But here, if it's not pled that any of these services provided by the representatives were actually billed by the doctor when the doctor had nothing to do with them.

MS. MAYER: That's not the theory here. The theory here is that the provision of the services themselves, product support services, was not acceptable when they were doing too much of it. And that's what's novel here, not grounded in the law. And again and I want to be clear, it's because the guidance and I do recognize the Advamed code is not long. We started with that concept, but it is industry guidance that neither OIG, nor DOJ, nor any court has ever suggested misstates the law or should be withdrawn and therefore, it is something that the industry generally follows as appropriate guidance and code.

You know, saying that the OIG as we talked about the provision of the phlebotomist or the laboratory, which is left by OIG, as long as the phlebotomist provides services that are consistent and related to the work that the outside laboratory is going to do with the specimens. I mean, there's nothing in that that says, oh, but if you do that on a routine basis for who you contract with, that's a problem. Or there's nothing in there that says you can't offer to

provide that, you have to wait for them to call you, right?

I mean, these are lines that Ms. Burke is creating to generate a case here being a good advocate for her client, but they're just not located in the law and then we're talking about where we draw the line both on what constitutes criminal conduct and what is sufficiently clear that you can infer that a defendant knew. Not just should have known, it's not a should have known standard, but actually knew he was engaged in illegal conduct when it went out and provided those product services. You need a lot more than is here and I submit the legal piece of this is very important, because you know, I'm not actually hearing that Ms. Burke can add a lot of details to the current Complaint and I think that's consistent with the fact that the amended Complaint didn't add a lot to the original Complaint. And you know, she did amend it and is acting in good faith here, I think. And she has said several times she believes her Complaint meets the pleading standards. There's been no change in the law. There's no cases for citing that have come down from the Amended Complaint that would suggest she wasn't on notice of some of the pleading standards.

I think the fact that there's no legal basis for this distinction between appropriate level of product services and too much product services shows that this is really incurable. Whether it's viewed either as a knowledge

failing and pleading that can't be cured or as just a straight up you can't enter in the law your theory sufficiently for it to be received. You can't, because that legal problem isn't going to change with discovery. You know, there isn't going to be law that you can cite to that was, you know -- that says here's what enough product support is, but here's what too much product support is for the purposes of this felony statute. And there's nothing that's going to change history in terms of what Medtronic knew about the ads, when it was deciding how much product support to provide.

THE COURT: Very well. Attorney Burke, final word?

MS. BURKE: Yes, your Honor, thank you. In essence, what defense counsel is asking you to do is make a determination akin to an OIG advisory opinion determination. But do so without the benefit of the adversarial process and the fact development. This is clearly an incidence in which the conduct itself fits within the rubric of the anti-kickback statute and there is a valid argument that we're dealing with kickbacks here.

Now, where they have to have gone into the OIG, they would have had to -- it's a case-by-case analysis and that's what the OIG does. And so, you are, in fact, you are the first decisionmaker on this, rather than the OIG. That's obviously Medtronic's -- a result of Medtronic strategically

deciding not to get an OIG advisory opinion. And you know, many times, companies don't want to be told no, so they'd rather take their chances. But in taking their chances, it then places you in the role of calling the balls and strikes on whether or not this is a kickback or not. Perfectly appropriate for you to do it, but it's not appropriate for you to do it based on a motion do dismiss and legal argumentation. It would benefit you in making that important call as to whether this is a kickback to have a factual record before you.

So, I would ask your Honor that you deny their motion that we move forward efficiently with discovery. Clearly there will be a summary judgment motion coming from Medtronic. We likely will put one forward on this legal issue, the facts to law issue that's before you, as well and get that ruled on sooner rather than later in the case. So, your Honor, we very much ask that you deny the motion.

THE COURT: Thank you very much. Anything else?

MS. MAYER: Yeah --

THE COURT: Sure.

MS. MAYER: -- all I want to say, because this is, it is a court case. You are not being asked to issue anything like an advisory opinion or an abstract, you know, regulation. You're not being asked to legislate what a line should be in this area critically -- action that's really

important here.

The burden of Ms. Burke, it's her burden, is to plead facts that demonstrate that a violation has occurred. Not that it might have occurred or it theoretically could have occurred or that -- and maybe let's take discovery and then we can all plan this really interesting factual playground and come up with a regulation or a regulatory decision that helps clarify this area. In order to sue in court, if she wants to do that, she has to go down to OIG and make a proposal that they issue a regulation clarifying that this kind of stuff, you know, is not okay if you do it beyond a certain level. There are lots of ways to get OIG to draw the line that she's wants the Court, through a jury trial, to draw here.

That is not appropriate use of the court and the fact that she's even suggesting that what she needs here is some sort of regulatory advice, I think proves that she hasn't stated a claim or can't state a claim here. That is her burden under Ashcroft and Iqbal and under all the 9(b) stuff. She has to be able to prove with facts, facts that Medtronic knew that it was providing an illegal bribe to doctors when it provided whatever "the more product support services" is than it should have provided. And you do not need to draw the line as to what is enough and what is too much here or even endorse the notion that that's a meaningful

distinction. What you are equipped to do here and it is appropriate here to do, is to ask has she met the burden of proving -- I'm sorry -- of pleading acts that, if true, demonstrate that Medtronic violated the anti-kickback statute, that it knew it was doing something illegal and it did so and that all claims resulted -- on a federal program, resulted from that conduct and it knew that that was the result. And she hasn't done it here and that's all that this Court has to do here with this case.

THE COURT: I think you're suggesting that the OIG existing advice to medical device providers, et cetera, it can't really be used as a shield by the defendants at this stage. It's not evidence of record and is not law, so even if it says that providing services that are related to the product, it is okay. That doesn't matter, because that's not the law we're looking at in trying to determine whether a claim's been made out.

MS. BURKE: It's slightly different. There's two different points. One is that Advamed, which is what counsel was relying on, is just an industry code that doesn't have any force of law.

The second is that the OIG, itself, has said that in-kind services can constitute kickbacks and there, they look at whether or not they're providing a substantial independent value. That's what we've alleged. We've alleged

that the services are being provided, they're giving a benefit to the doctor and it rises to the level of a kickback.

THE COURT: I mean, well, let me, because this is an important point for me. It may not seem so to the two of you, but so we're all relying on this whole idea of substantial, independent value to purchaser. That's independent of the product support, correct?

MS. BURKE: No, it's not independent -- the word independent does not mean independent of the product support, it means are you giving a benefit to the -- a bribe, are you giving a bribe to the -- so it can be in the form. It can be linked to the product and still be an independent benefit to the provider.

THE COURT: Okay.

MS. BURKE: And so, for that reason, that's what we've alleged. And defense counsel is saying, well, we can't cite to any case where these have been found to be kickbacks.

THE COURT: But are you conceding that there is this, what you refer to as this loophole that there is this, that Medtronic has the right to provide product services?

MS. BURKE: No, no, your Honor. We don't concede that because it doesn't exist. What I'm saying is that the state of the law now, is that there is the kickback statute itself, which sweeps in a broad array of conduct, including

the conduct at issue here. So, it is facially kickbacks. There are then --

THE COURT: So, then that's, so you're saying even the type of service is a kickback?

MS. BURKE: Exactly.

THE COURT: Because that's got a bearing 404, it's not just the amount, the quantum of services.

MS. BURKE: Right.

THE COURT: But now the type of service, even if it's related to the pacemaker or to the defibrillator, that is still, in and of itself or just that one time, that could be a violation of the anti-kickback statute?

MS. BURKE: Exactly. There is facially it all meets the kickback test of the statute. So --

THE COURT: If you just read that simple language.

MS. BURKE: Exactly.

THE COURT: In-kind service, because that was remuneration.

MS. BURKE: And so, your Honor, so the kickback, because it is a broad statute, then there are different ways to out from under its scope. And there you have the delineated safe harbors. This conduct doesn't fit into any of those delineated safe harbors. Even the OIG has said, however, that even if there's not a safe harbor that covers you, you may be able to prove it's not a kickback because it

has no intent to corrupt and no corrupting influence on the doctors. So, it becomes a case-by-case analysis as to whether or not it's the kickback.

And so, your Honor, that it's caught by the law and it's not insulated from liability. So, what we've alleged is there's a pattern, there's a scheme, it's happening all over the country and it's all caught by the terms of the kickback law. They're arguing obviously, no, we should -- you know, it's permissible. And what I'm saying is that just as you can't rule as a matter of law right now, well, definitionally, it fits within the rubric, so therefore, clearly there's liability. You also can't do the reverse and say, oh, you know, well, they think it's permissible product support and therefore, you know, they're home free. So, I'm just suggesting, your Honor, that that is the issue, the central issue of this lawsuit. We do not know in advance how it will come out because it is, in fact, an issue of first impression.

THE COURT: Okay. Oh, I knew you had to respond to that. I was just taken us back. We went forward so many steps and I just took us back many.

MS. MAYER: It's a little bit like I became a moving target here. But I want to make sure we understand the averred position that she has just stated with respect to what the way the anti-kickback statute versus what we've had

today.

She is saying that all product support, because it is in-kind services, all product support is a kickback unless it falls within a safe harbor. What that means is the FDA approvals require the company to provide technical support and training for the product. That violates the anti-kickback statute, it doesn't fall within a safe harbor. So, that means the company gets to choose whether it complies with FDA or commits a felony on Ms. Burke's theory of how this stuff works.

Number two, having even a helpline for doctors to ask questions is an in-kind service, because if they didn't ask the company, they'd have to go pay some expert to be able to provide them the answers. So, that also violates the anti-kickback statute, providing truthful and accurate information without reimbursement violates the anti-kickback statute because otherwise it's an in-kind service and in-kind assistance in patient support that is disallowed under the plain language of the anti-kickback statute and you have to get an OIG opinion or find a way to get a safe harbor to protect it.

You know, the scheme that she's articulating, all of these things which OIG has said it's fine to do, which Advamed has said from 2009, is fine to do. It turns out everybody have been running around committing felonies, okay?

She wants to litigate a novel issue here because there's no case otherwise, because it's -- and it's absurd, because the notion that a medical device manufacturer, once it manufactures its product, has to do this. Even the FDA tells them they have to train and support it. Even when the industry has given us a litany of things that are permissible to do, even when OIG, since 1994, which is many years ago, it's saying you can provide services in connection with your services, as long as they're confined to that same purchase. So, all of that is non-binding which means that as a Court, you're obliged to apply the anti-kickback statute to say that this stuff was a felony. I mean, it is -- it boggles the mind. And the legal reasons why she's wrong is because OIG drafted the safe harbor regulations is entitled to go out with guidance that has been uncontradicted. There's no evidence in any of the record in front of the Court, that contradicts any of this, has said more than once, product support is outside the scope if it's connected to the product. You have remuneration and therefore, fall within the ambit of the anti-kickback statute only when you're giving in-kind service that provides a substantial value and is independent of the product itself.

So, when OIG says that and I want to talk a little bit about, I mean, it's not just the Advamed code, I want to talk a little bit about the 2003 Compliance Act. This was a

document that OIG put out for the entire pharmaceuticals. There isn't the medical device one and so, as a practical matter, device companies look to their pharma guide for, you know, where applicable for assistance as it applies here. So and this is for pharmaceutical companies and they're selling pills which are much less complex from an administration perspective, a technological medical device, right, that is implanted and all that kind of stuff. It has to be programmed individually for the patient when it's implanted. And might have to be adjusted with different computer software and algorithm at these check-up visits that she insists are routine.

I think the key here is that basic to OIG, who defined the safe harbors, who enforces the statute in the first instance and the regulatory safe harbors, is saying product support is fine, you can give product support. You know, that's not what we are talking about with respect to remuneration. And that interpretation of the anti-kickback statute is entitled to that. Especially, when it's in a formal document like the OIG Compliance Act. We haven't briefed that law -- if we need to do supplemental briefing on this, we can do it, I think, because I understand your Honor is, you know, looking at applying the law.

I think the key here is that all the evidence is that what Medtronic knew going into this, is that product

support has been blessed by the relevant regulators and by the industry expert and nobody was kicking up a fuss about those blessings. I mean, the anti-kickback statute. Under those circumstances, when we're evaluating whether, again, whether anything, any remuneration has been provided, whether we're trying to interpret whether it's permissible or appropriate for a court to interpret the statute and conclude product support services as remuneration, I think it would be a, you know, a judge can interpret the law, it would be a novel interpretation that runs contrary to what the regulators and others said how it should be interpreted to do that.

The Court has the ability to do that if it wants to. I think if the Court were inclined to do that or hesitant to make a definitive ruling, I fall back again on knowledge. It is clear regardless that nobody has interpreted the anti-kickback statute in case law or otherwise, to take the position that Ms. Burke is taking here today, that all product support services, by definition, are in-kind services that fall within the anti-kickback statute absent no going and meaning a safe harbor or getting an OIG opinion. And so, at the most basic level, she has to plead facts demonstrating she can prevail on every element of the anti-kickback statute as well as the subsequent False Claims Act violation. She cannot plead it and prove and critically, the motion to

dismiss, she cannot plead that Medtronic knew that it was acting illegally when it provided product support services it has given, which OIG has said, Advamed has said and the fact that nobody has kicked up a fuss about it in 20 years. Medtronic is entitled to have an expectation that what they say is okay to do, is okay to do. So, if they don't say you can only do so much of it and not more, is Medtronic entitled to believe that you could do what you wanted to do with this product and not prohibited.

THE COURT: Okay, anything else?

MS. BURKE: Your Honor, just a final word?

THE COURT: Sure.

MS. BURKE: Again this notion that somehow because it's novel, you can't let the case go forward. That's not the way it works. In the health care industry, every single practice that has been deemed to be a kickback was subject to the very same defense argument. Every single time that the argument is always, well, you know, no one stopped us yet, so therefore, it must be permissible. You know, that happened with the lunches to the doctors, it happened on the speakers bureaus, it happened in the pharmaceutical industry. So, that argument simply is basically and admission that they're doing it and no one was blowing the whistle on them. Well, the whistle's now been blown on them and the conduct, whether or not it fits within the rubric of the kickback statute,

turns in part on the intent. Whether they intended to induce the purchasers of the device, whether they intended to impact their purchasing. We've pled that they have. We've pled the facts of how they did that, of what they provided, that it was frequent and the like.

So, we have pled all the requirements and merely saying, well, gee, we thought we were doing something that was okay is not a legal defense. So, again, your Honor, we ask that you deny the motion, thank you.

THE COURT: Okay, thank you. Counsel, thank you very much. This has been very helpful. I know you have distances to travel and I hope you have safe travels, but if you are looking for lunch, here in Easton, we have some fantastic restaurants, including if you just exit the courthouse, the building and go to the left, there is Italian, then there's seafood. Right next to that it's Mexican, all within a very short walking distance, especially on such a nice day. In fact, if you have any questions about them, I'm sure Jamie Kulick, my criminal deputy here would be glad to guide you to an appropriate restaurant. But have a great rest of the day and thank you for the argument.

ALL: Thank you, your Honor.

THE DEPUTY CLERK: All rise.

(Proceeding adjourned 12:45 o'clock p.m.)

* * *

CERTIFICATION

I hereby certify that the foregoing is a correct transcript from the electronic sound recording of the proceedings in the above-entitled matter.

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